



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 30 1998

Food and Drug Administration
Washington, DC 20204

2327 '99 JAN -5 P2:12

Mr. Rob Maltas
VP Product Development
The Winning Combination
430 Parkson Road
Henderson, Nevada 89015

Dear Mr. Maltas:

This is in response to your letters to the Food and Drug Administration (FDA), dated December 16 and 18, 1998, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that The Winning Combination is making certain statements for the products "The Ultimate Fat Fighting Gourmet Snack Bar," Aloe Cranberry+Plus, and "The Ultimate Fat Fighting Drink, products you assert to be dietary supplements.

These products are not dietary supplements within the meaning of 21 U.S.C. 321(ff). These products are conventional foods.

"The Ultimate Fat Fighting Gourmet Snack Bar" is represented as a "snack bar," "a small meal disguised as a candy bar," and "a healthy low-calorie meal or snack bar." It is also represented for use as a meal replacement in that it is to be used "for one or two of those small meals" that should be eaten throughout the day and to be used by persons who "normally skip breakfast;" this product is proposed to be an alternative to "get off to a great start by eating an Ultimate Fat Fighting Bar along with a glass of juice, milk or water." The Ultimate Fat Fighting Bars are also represented "as the perfect solution" to "ordering take-out or fast food several times a day" or "convenient junk food" used to provide "the most difficult meals or snacks" during the day.

"Aloe Cranberry+Plus" is represented as a "beverage" and a "low calorie, fat-free, delicious drink."

"The Ultimate Fat Fighting Drink" is represented to be a "small meal disguised as a delicious beverage," "a delicious, healthy, low-calorie, low-fat meal or snack," "a quick snack," and as a "far healthier and nutritious alternative than skipping a meal entirely or resorting to candy or fast food."

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Page 2 - Mr. Rob Maltas

21 U.S.C. 321(ff) states, in part, that the term dietary supplement means a product that “is not represented for use as a conventional food or as a sole item of a meal or the diet.” Therefore, if you intend to market these products as dietary supplements, the references on the label or in the labeling that these products are intended for use as conventional foods, beverages, meal replacements, or alternatives to other conventional foods must be removed.

In addition, you state that you are making the claim for the product “Aloe Cranberry+Plus” that aloe “has been used for centuries as a topical remedy to soothe skin irritation, burns and sunburn.” 21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA’s Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

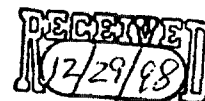
Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, San Francisco District Office, Compliance Branch, HFR-PA140



430 Parkson Road
Henderson, Nevada 89015
702-564-9000 FAX 702-564-7829

December 18th 1998



Director
Special Nutritionals
Center for Food Safety and Applied Nutrition
FDA
200 C Street S.W.
Washington, DC 20204

Dear Sir / Madam:

This is a 30-day notification for a dietary supplement that will be on the market within 30 days. The product name is **The Ultimate Fat Fighting Gourmet Snack Bar**. The claims on the 10 and 24 count packages are identical and are:

"The Ultimate Fat Fighting Gourmet Snack Bar

This exciting new food supplement tastes exactly like a candy bar but is actually a small meal disguised as a candy bar, perfectly balanced for protein, fat, carbohydrate and other essential vitamins and minerals. Based on the popular 40/40/20 nutrition concept (40 percent of calories from protein, 40% from carbohydrate and 20% from fat). The **Ultimate Fat Fighting Bar** is a healthy low-calorie meal or snack bar. It contains only 150 calories, but because it's low in carbohydrate and has only three grams of fat, it delivers 15 grams of high quality protein.

Recent breakthroughs in fat-loss technology suggest that we should eat small meals more frequently throughout the day. Unfortunately, eating five or six small healthy meals a day can be quite difficult, especially when you try to balance fat, protein and carbohydrate. The **Ultimate Fat Fighting Bar** makes achieving this much more convenient. With the **Ultimate Fat Fighting Bar**, one or two of those small meals can now be quick, convenient, inexpensive and very satisfying. If you normally skip breakfast, (one of the worst mistakes you can make on any fat-loss program), now you can get off to a great start by eating an **Ultimate Fat Fighting Bar** along with a glass of juice, milk or water.

When you eat every three or four hours throughout the day, the most difficult meals or snacks are the ones occurring mid-morning and mid-afternoon. Those are the times most of us find ourselves too busy to prepare something healthy, so we often reach for convenient “junk food.” This can get expensive if your only alternative is ordering take-out or fast food several times a day. The **Ultimate Fat Fighting Bars** offer the perfect solution. They are quick, great tasting, convenient, and perfectly balanced in terms of protein, carbohydrate and fat. The **Ultimate Fat Fighting Bars** serve a dual purpose of increasing energy levels*, while taking the edge off your appetite for the next meal.

Each **Ultimate Fat Fighting Bar** contains Garcinia Cambogia, which may help suppress your appetite and reduce the conversion of carbohydrate to fat. The **Ultimate Fat Fighting Bar** also contains Citrus Aurantium, a standardized extract of bitter orange. Finally, we add Chromium polynicotinate and Vanadyl sulfate to support healthy carbohydrate metabolism.

Use **Ultimate Fat Fighting Bars** to help you maintain energy while you achieve your weight loss goals!

* Energy claims based bar's 150-calorie energy content.”

Respectfully Submitted,

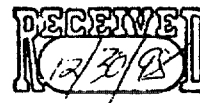
A handwritten signature in black ink, appearing to read 'Rob Maltas', with a large, stylized flourish extending from the end of the signature.

Rob Maltas
VP Product Development



430 Parkson Road
Henderson, Nevada 89015
702-564-9000 FAX 702-564-7829

December 16th 1998



Director
Special Nutritionals
Center for Food Safety and Applied Nutrition
FDA
200 C Street S.W.
Washington, DC 20204

Dear Sir / Madam:

This is a 30-day notification for a dietary supplement that will be on the market within 30 days. The product name is **Aloe Cranberry+Plus**. The claims on the 1 lb., 50 serving container are:

"**ALOE CRANBERRY+PLUS** is a soothing, healthy, nutritious drink delivering the highest quality extract of one of the most widely used traditional remedies in existence today – **ALOE VERA**. Our concentrated Aloe Vera is derived from the inner filet of the *Aloe Vera Barbadosensis* plant. They are cultivated in exceptionally fertile soil and never exposed to frost during growth, or heat during the extraction process. It requires over twelve pounds of aloe gel to extract just one ounce of the exceptionally high quality 200:1 aloe concentrate powder found in this beverage. Aloe has been used for centuries as a topical remedy to soothe skin irritation, burns and sunburn. Aloe's ancient history of internal use includes supporting the body's natural defense mechanisms, soothing the stomach and gastrointestinal tract and as a natural anti-inflammatory substance. After centuries of use, aloe remains one of the most popular folk remedies in use today. The "Plus" in **Aloe Cranberry+Plus** relates to the seven important herbs that are synergistically blended with aloe to deliver an even more soothing, healthy and nutritious aloe drink. Specifically, we add Cranberry Extract because of it's high concentration of antioxidants and the natural healthy support it provides to the urinary tract. We also add standardized extracts of Ginger, Deglycyrrhizinated Licorice, Fenugreek and Chamomile because of their widespread use in traditional herbal formulas to soothe the stomach and gastrointestinal tract. Lastly, Grape Skin Extract and Milk Thistle Extract have also been added because of their high concentration of certain antioxidants, particularly those of Milk Thistle, which target the liver. Our **Aloe Cranberry+Plus** is truly a comprehensive combination of Mother Nature's most soothing, natural herbal components providing everything you want from an Aloe drink, and more. Enjoy this low calorie, fat-free, delicious drink and the health benefits it provides."

Respectfully Submitted,

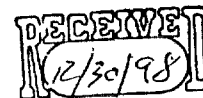
Rob Maltas
VP Product Development



THE WINNING COMBINATION

The Informed Choice

430 Parkson Road
Henderson, Nevada 89015
702-564-9000 FAX 702-564-7829



December 16th 1998

Director
Special Nutritionals
Center for Food Safety and Applied Nutrition
FDA
200 C Street S.W.
Washington, DC 20204

Dear Sir / Madam:

This is a 30-day notification for a dietary supplement that will be on the market within 30 days. The product name is **The Ultimate Fat Fighting Drink**. The claims on the 10 and 30 serving containers are identical and are:

"THE ULTIMATE FAT FIGHTING DRINK is a delicious new weapon in the war against fat. It may taste like a vanilla shake, but it is actually a small meal disguised as a delicious beverage, perfectly balanced for protein (15 grams), carbohydrate (15 grams), fat (only 3 grams) and other essential vitamins and minerals. At only 150 calories and based upon the popular 40/40/20 nutrition concept (40% of calories from protein, 40% from carbohydrate and 20% from fat), **The Ultimate Fat Fighting Drink** can be used as a delicious, healthy, low-calorie, low-fat meal or snack.

The Ultimate Fat Fighting Drink makes those difficult mid-morning and mid-afternoon hunger pangs a thing of the past. Now a quick snack is healthy, convenient, inexpensive and very satisfying. This snack serves the dual purpose of increasing energy levels while also taking the edge off your appetite for the next meal. Since experts recommend eating several small meals throughout the day, **The Ultimate Fat Fighting Drink** provides a far healthier and nutritious alternative than skipping a meal entirely or resorting to candy or fast food.

The Ultimate Fat Fighting Drink also contains HCA from a standardized extract of the Garcinia Cambogia fruit which may help suppress your appetite and reduce the conversion of the carbohydrate calories you eat to body fat. **The Ultimate Fat Fighting Drink** also contains Citrus Aurantium*, a standardized extract of the bitter orange. Finally, in addition to 18 other vitamins and minerals, including Vanadyl Sulfate, we also provide Chromium Polynicotinate to support healthy carbohydrate metabolism.

**Use the Ultimate Fat Fighting Drink to help sustain your energy
levels while you healthily achieve your weight loss goals!"**

Respectfully Submitted,

Rob Maltas
VP Product Development